REMARKS/ARGUMENTS

Claims 20, 21 and 24 have been amended. Claims 1-5, 8-19, 22, 25 and 28 have been allowed. Claims 1-5 and 8-29 remain pending in this application upon entry of this amendment.

Support for the Present Amendments

Claim 20 has been amended to delete the phrase "function-conservative variants" from the claim.

Claim 21 has been amended to recite "a method for the identification of DNA sequence variations in a region of the C2/4GnT gene" and to recite that the segment of the patient's DNA that is amplified comprises a region that is "at least 95% identical to a subsequence of SEQ ID NO: 1 selected from the group consisting of nucleotides 1-245, nucleotides 246-435, and nucleotides 436-2319 of SEQ ID NO: 1." Claim 24 has been amended in a manner similar to claim 21. Claim 24 has also been amended to fix an obvious typographical error ("C2/C4GnT" to "C2/4GnT').

Support for amplification of regions of the C2/4GnT gene can be found throughout the specification and in particular on page 3 lines 15-16, page 4 lines 28-33, page 6 lines 14-17, page 12 lines 28-31 and page 22 lines 20-24. For example page 12 lines 28-31 reads:

> Described in Example 6 below is a method for scanning the coding exon for potential structural defects. Similar methods could be used for the characterization of defects in the non-coding region of the C2/4GnT gene including the promoter region.

Support for regions of the C2/4GnT gene having at least 95% sequence identity with a subsequence of SEQ ID NO: 1 selected from the group consisting of nucleotides 1-245, nucleotides 246-435, and nucleotides 436-2319 can be found throughout the specification and in particular in originally filed claim 6, in Figure 2 of the application and on page 3 lines 17-18, page 9 lines 7-10, and page 19 lines 10-11 of the specification. Specifically, originally filed claim 6 describes nucleotide sequences comprising nucleotides 1-245, nucleotides 246-435 and nucleotides 436-2319 of SEQ ID NO: 1.

No new matter has been added by way of these amendments.

Rejections under 35 U.S.C. § 112, second paragraph

Claim 21 was rejected for indefiniteness. The Examiner alleges that the phrase "amplified genomic regions are at least 95% identical to SEQ ID NO: 1" is not clear because SEQ ID NO: 1 does not correspond to genomic sequences (i.e. both introns and exons) of C2/4GnT.

Without conceding the Examiner's position, claim 21 has been amended to recite that it is "a region of the C2/4GnT gene" in which variations are detected. The claim requires that the amplified DNA comprises a region "that is at least 95% identical to a subsequence of SEQ ID NO: 1 selected from the group consisting of nucleotides 1-245, nucleotides 246-435, and nucleotides 436-2319 of SEQ ID NO: 1." These regions, for example shown in Fig. 2 and in originally filed claim 6, make up the entire sequence of SEQ ID NO: 1.

Claim 21 clearly defines and points out the claimed subject matter, i.e. a method for the identification of DNA sequence variations in a region of the C2/4GnT gene, said region being at least 95% identical to a subsequence of SEQ ID NO: 1 selected from the group consisting of nucleotides 1-245, nucleotides 246-435, and nucleotides 436-2319 of SEQ ID NO: 1. Accordingly, this rejection has been overcome and Applicants respectfully request its withdrawal.

Rejections under 35 U.S.C. § 112, first paragraph

Claims 21 and 24 have been rejected for failure to fulfill the enablement requirement because the specification allegedly does not teach how many exons exist in the C2/C4GnT gene, the sequence of each of the exons, and mismatch mutation.

Without conceding the Examiner's position, claims 21 and 24 have been amended to recite that it is one or more specific regions of the C2/4GnT gene in which variations are to be detected. Specifically, claim 21 has been amended to recite that the regions are "at least 95% identical to a subsequence of SEQ ID NO: 1 selected from the group consisting of nucleotides 1-245, nucleotides 246-435, and nucleotides 436-2319 of SEQ ID NO: 1." These regions of the C2/4GnT gene make up the entire SEQ ID NO: 1 sequence and are supported in originally filed claim 6. In addition, the phrase "mismatch mutation" has been deleted from claim 21. Accordingly, these rejections have been obviated and their withdrawal is respectfully requested.

Claim 20 has been rejected for alleged failure to fulfill the written description and enablement requirements because the Examiner contends that the specification does not sufficiently describe "function-conservative variants" and because it would allegedly require undue experimentation for one skilled in the art to identify such variants. Applicants respectfully do not agree; "function-conservative variants" are described and enabled by the present application (see for example page 8 lines 6-11 of the specification). However in order to advance prosecution of the present application, the phrase "function-conservative variant" has been deleted from claim 20, without prejudice or disclaimer. Accordingly, these rejections have been obviated and their withdrawal is respectfully requested.

Claim 23 and its dependent claims (claims 26, 27 and 29) have been rejected for failure to fulfill the written description requirement. The Examiner contends that the specification does not adequately describe all possible DNA sequences that comprise fragments of SEQ ID NO: 1.

Applicants respectfully traverse this rejection. Claim 23 depends from claim 1 which recites any nucleic acid encoding the particular polypeptide "or an enzymatically active fragment thereof." Claim 1 has been allowed as it is now written. See Applicants' Response Mailed January 22, 2003, p. 13 first full paragraph. Claim 23 incorporates all the limitations of claim 1 including the limitation that the encoded fragment be enzymatically active. Thus, claim 23 is not directed to "all DNA fragments of SEQ ID NO: 1" (see last paragraph p. 8 Action) or "a large variable genus with the potentiality of encoding many different proteins" (see paragraph 1 p. 9 Action), as contended by the Examiner. Rather, claim 23 is directed to

isolated nucleic acids comprising nucleotides 634-1812 of SEQ ID NO:1 or sequence-conservative variants thereof, which encode C2/4GnT having the amino acid sequence SEQ ID NO: 2 or an enzymatically active fragment thereof. Sequence-conservative variants are clearly defined in the specification as variants in which "a change of one or more nucleotides in a given codon position results in no alteration in the amino acid encoded at that position" (page 8 lines 4-6 of the specification; emphasis added). This definition is a description that what applicant possessed was the group of nucleic acid molecules comprising a segment encoding the polypeptide of Fig. 2 or active fragments of the polypeptide. This description coupled with the amino acid sequence of Fig. 2 and the corresponding nucleotide sequence of Figure 2 constitutes a description of the scope of claim 23. Thus, claim 23 and its dependent claims clearly encompass only those polynucleotides encoding the polypeptide of SEQ ID NO: 2 or fragments of said polypeptide having enzymatic activity. This group of DNAs is fully described and enabled and should be allowed for the same reasons as claim 1. Accordingly, withdrawal of this rejection is respectfully requested.

Proposed New Claim

Applicants would like to present a proposed new claim. Applicants would not like proposal of this new claim to prevent the present amendment from being entered by the Examiner. Applicants respectfully request and authorize entry of this proposed claim by way of Examiner's Amendment.

Proposed New Claim:

An isolated nucleic acid encoding UDP-N-acetylglucosamine: galactose-β1,3-N-acetylgalactosamine-α-R/N-acetylglucosamine-β1,3-N-acetylgalactosamine-α-R β1,6-N-acetylglucosaminyl-transferase (C2/4GnT), wherein said nucleic acid comprises a nucleotide sequence that is more than 90% identical to nucleotides 1-2319 of SEQ ID NO: 1.

Support for this proposed new claim can be found throughout the specification, and specifically, for example, in originally filed claims 1 and 5 and on page 9 lines 9-10 of the specification.

If entry of this claim would preclude entry of this Amendment, Applicants request entry of this Amendment without entry of this claim and that all pending claims be allowed and the case passed to issue.

Conclusion

In view of the above amendments and remarks, it is respectfully requested that the application be reconsidered and that all pending claims be allowed and the case passed to issue. If there are any other issues remaining which the Examiner believes could be resolved through

either a Supplemental Response or an Examiner's Amendment, the Examiner is respectfully requested to contact the undersigned at the telephone number indicated below.

Respectfully submitted,

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Dated: July 22, 2003

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